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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,803	11/14/2005	Giuseppe Arpaia	279737US0PCT	1463

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
XU, XIAOYUN	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/556,803	ARPAIA ET AL.	
	Examiner	Art Unit	
	ROBERT XU	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-24* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on 10/09/2008 has been entered and fully considered. Claims 1-14 are canceled. Claims 15-24 are pending in the application.

2. The rejection is modified upon reconsideration of the case.

Claim Objections

3. Claim 23 is objected to because of the following informalities: "100 pg/ml" should be "100 μg/ml". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 15 -17 and 22-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Katakam et al. (Pharmaceutical Development and Technology, 1997) (Katakam)

In regard to Claim 15, Katakam teaches the use of Poloxamer polymer to stabilize recombinant human growth hormone (rhGH) against various processing stress (see title). The method comprises:

mixing the protein sample (rhGH) by adding a Poloxamer to the sample (see page 144, right col., 3rd paragraph);

performing chromatography (size exclusion column- HPLC) on the protein sample (see page 145, right col. 1st paragraph); and

the quantity of the protein is determined by UV absorbance of the eluted protein solution (see page 145, right col. 1st paragraph and Figure 1-2).

Katakam does not specifically teach using data from calibration with a standard to calculate the quantity of the protein. However, using data from calibration with a standard to calculate the quantity of the protein is well known in the art. At time of the invention, it would have been obvious for a person of ordinary skill in the art to use data from calibration with a standard to calculate the quantity of the protein.

In regard to Claim 16, simple dilution of protein sample to a level acceptable for the chromatographic system is well-known in the art.

In regard to Claim 17, Katakam teach using size-exclusion chromatography (SEC) to quantify protein (see page 145, right col. 1st paragraph).

In regard to Claim 22, Katakam teaches using Pluronic F68 to stabilize protein (Table 1).

In regard to Claim 23, Katakam tests various concentrations of Pluronic F68 in the range from 0.001% (below cmc) to 0.2% (above cmc) (see Table 1). The concentration of 100 μg/ml is equivalent to 0.01%. Katakam's teaching meets the recited limitation.

6. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Katakam in view of Wen (Analytical Biochemistry, 1996).

In regard to Claim 18, Katakam does not teach dimeric glycoprotein. Wen teaches that Stem cell factor (SCF) is a dimeric glycoprotein. Wen studies the SCF by size-exclusion chromatography (see page 159, left col., lines 12-18, Figure 4). At the time of the invention, it would have been obvious to one of the ordinary skill in the art to add Poloxamer to the dimeric glycoprotein sample for size exclusion chromatography to improve the yield, because Katakam teaches that Poloxamer polymer can stabilize protein against various processing stress.

7. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Katakam in view of Wu (Journal of Endocrinology, 1993).

In regard to Claim 19, Katakam does not teach FSH. Wu teaches that FSH from bovine pituitary glands is isolated by size exclusion (gel filtration) chromatography (see abstract). At the time of the invention, it would have been obvious to one of the ordinary skill in the art to add Poloxamer to the FSH sample for size exclusion chromatography to improve the yield, because Katakam teaches that Poloxamer polymer can stabilize protein against various processing stress.

8. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Katakam in view of Arduini (Protein Science,1999).

In regard to Claims 20 and 21, Katakam does not teach interferon. Arduini teaches that Interferon bata-1a is isolated by size exclusion (gel filtration) chromatography (see abstract). At the time of the invention, it would have been obvious to one of the ordinary skill in the art to add Poloxamer to the Interferon bata-1a sample for size exclusion chromatography to improve the yield, because Katakam teaches that Poloxamer polymer can stabilize protein against various processing stress.

9. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Katakam in view of Toschi (European Journal of Biochemistry, 1998).

In regard to Claim 24, Katakam teaches that the most effective concentration of Poloxamer is above cmc, or up to 0.2%. Katakam does not teach that Pluronic F68 is added in sodium acetate buffer at pH 3.8 in the protein solution. Toschi teaches that elution buffer of 0.01% Pluronic F68 and 50 mM sodium acetate, pH 4 is used in protein purification by chromatography (see page 109, left col., lines 28-33). Toschi does not teach that elution buffer comprises 0.1% Pluronic F68. The court has held that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (*In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). Toschi teaches the concentration of Pluronic F68 is 0.01% and Katakam teaches the most effective concentration of Pluronic F68 is up to 0.2%. It would have been obvious for a person of ordinary skill in the art to optimize the concentration of Pluronic F68 in protein solution to be 0.1% by routine experimentation.

Response to Arguments

10. Applicant's arguments with respect to claims 15-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/5/2008

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

RX